P184 Prospective real-world experience with cabozantinib in patients with advanced renal cell carcinoma: Interim results of the Belgian REPLICA study

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Introduction & Objectives: Cabozantinib (Cabo) is a well-established agent in the treatment landscape for patients with advanced Renal Cell Carcinoma (aRCC). It is approved as monotherapy in first line [only for patients with an intermediate or poor International Metastatic RCC Database Consortium (IMDC) risk classification] and following a prior treatment regimen including a Vascular Endothelial Growth Factor (VEGF)-directed targeted therapy. In addition, the combination of Cabo and nivolumab is indicated as first line treatment for aRCC patients, across all IMDC risk categories. The descriptive, prospective, and non-interventional REPLICA study assessed the performance of Cabo across different treatment lines in a Belgian real-life setting.

Materials & Methods: REPLICA aims to include 150 aRCC patients treated with Cabo, alone or in combination. Here we report the interim efficacy results with Cabo monotherapy (Cabo Mono, N=61), with a specific focus on patients receiving this treatment in the 2nd line setting (Cabo 2nd line, N=43), the largest patient subgroup in this study.

Results: Patients receiving Cabo monotherapy across different treatment lines (n=61) had a median age of 69 years; 72% were male; 68.9% had metastatic disease (stage IV) at RCC diagnosis; 80.3% had a tumor with a clear-cell histology and 55.7% of patients underwent prior nephrectomy. The majority of patients receiving Cabo 2nd line (n=43) were previously treated with a dual immunotherapy (48.8%) or immunotherapy + tyrosine kinase inhibitor (48.8%) combination in first line. None of these patients obtained a Complete Response (CR) to this first line treatment, but a partial response (PR) as best response was seen in 57.9%. The median Progression-Free Survival (PFS) among all patients receiving Cabo monotherapy in this study was 7.6 months (95% CI: 4.5 – 8.6 months). The Objective Response Rate (ORR) was 27.3% (all PR), with an additional 25.5% experiencing Stable Disease (SD), for a Disease Control Rate (DCR) of 52.7%. Among patients with clear-cell histology subtype, the median PFS was 7.9 months. Partial response, SD and DCR were reported at 32.6%, 25.6% and 58.1%, respectively. In patients who received Cabo in 2nd line, the median PFS reached 7.6 months, with an ORR and DCR of 23.7% and 47.4% respectively. These findings are very similar to the 7.4 months median PFS demonstrated in the pivotal METEOR study.

Conclusions: These real-world data with Cabo in REPLICA study confirm the results of the registrational METEOR trial, with a median PFS of 7.6 months and DCR in more than half of the patients. As such, these findings further solidify Cabo as a valuable 2nd line treatment option in aRCC patients.